IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
SUN PHARMACEUTICAL INDUSTRIES LIMITED and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
	)	
Defendants.	)	

COMPLAINT

Pfizer Inc. ("Plaintiff" or "Pfizer"), for its Complaint against Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively "Sun"), alleges as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Sun for infringement of United States Patent No. 9,937,181 (the "'181 patent").

2. This action arises out of Sun Pharmaceutical Industries Limited's filing of ANDA No. 209790 seeking approval by the FDA to sell generic copies of Xeljanz XR® (tofacitinib extended release tablets, 11 mg) prior to the expiration of the '181 patent.

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. On information and belief, defendant Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India, having its principal place of business at CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, India 400063.

5. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan, having its principal place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited. On information and belief, Sun Pharmaceutical Industries, Inc. is the U.S. agent for Sun Pharmaceutical Industries Limited and for ANDA No. 209790.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Sun by virtue of the fact that, *inter alia*, Sun has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiff, including in Delaware. In particular, this suit arises out of Sun Pharmaceutical Industries Limited's filing of ANDA No. 209790 seeking FDA approval to sell tofacitinib extended release tablets, 11 mg ("Sun Generic XR Tablets") prior to the expiration of the '181 patent, throughout the United States, including in Delaware.

8. On information and belief, Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. are agents of each other and/or work in concert with each other on the development, obtaining of regulatory approval, marketing, sale, and/or distribution of generic drugs, including Sun Generic XR Tablets, throughout the United States, including in or into Delaware. On information and belief, Sun Pharmaceutical Industries Limited, directly or

through its subsidiary Sun Pharmaceutical Industries, Inc., manufactures, markets, imports, and sells generic drugs for distribution in Delaware and throughout the United States.

9. On information and belief, if ANDA No. 209790 is approved, Sun Generic XR Tablets will, among other things, be marketed and distributed by Sun in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

10. Sun's infringing activities with respect to its filing of ANDA No. 209790 and its intent to commercialize and sell Sun Generic XR Tablets has led and/or will lead to foreseeable harm and injury to Pfizer, which is incorporated in Delaware.

11. On information and belief, Sun maintains substantial, systematic and continuous contacts throughout the United States, including in Delaware. Sun's website states that "[i]n the US market, which contributes a significant share of our revenues, we are the leader in the generic dermatology segment. We have strong capabilities in developing generic and complex products." (http://www.sunpharma.com/business-development (last visited Sept. 27, 2018)). Upon information and belief, Sun has distribution and customer service teams at multiple locations across the United States.

12. Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. have previously availed themselves of this Court by consenting to this Court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Galderma Labs., L.P. et al. v. Sun Pharm. Indus. Ltd. et al.*, No. 1:16-cv-01003-LPS (D. Del.) (D.I. 11) (Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. submitted counterclaims and did not contest personal jurisdiction); *Pfizer Inc. et al. v. Sun Pharma Global Inc. et al*., No. 1:09-cv-00313-GMS (D. Del.) (D.I. 13) (same).

13. Sun has not contested personal jurisdiction in Civil Action Nos. 1:17-cv-00159-LPS and 1:17-cv-01597-LPS, pending actions that Pfizer has brought against it in this Court, arising out of Sun's filing of the same ANDA that gives rise to this action.

14. In the alternative, this Court has jurisdiction over Sun Pharmaceutical Industries Limited under Federal Rule of Civil Procedure 4(k)(2). Sun Pharmaceutical Industries Limited has contacts with the United States by, *inter alia*, having filed its ANDA with the FDA.

15. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

16. Sun has not contested venue in Civil Action Nos. 1:17-cv-00159-LPS and 1:17-cv-01597-LPS, pending actions that Pfizer has brought against Sun in this Court, arising out of Sun's filing of the same ANDA that gives rise to this action.

BACKGROUND

Xeljanz XR

17. Pfizer holds approved NDA No. 208246 for EQ 11 mg base tofacitinib citrate extended release tablets, which it sells under the registered name Xeljanz XR. The active ingredient in Xeljanz XR is tofacitinib citrate. Xeljanz XR contains tofacitinib citrate in an amount equivalent to 11 mg of tofacitinib base in an extended release tablet formulated for once-daily administration.

18. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated, *inter alia*, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

19. The FDA-approved Prescribing Information for Xeljanz XR states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d]

pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz XR

20. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '181 patent is listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz XR NDA.

21. The Orange Book lists the expiration date for the '181 patent as March 14, 2034.

22. Sun's prior Paragraph IV notices in Civil Action Nos. 1:17-cv-00159-LPS and 1:17-cv-01597-LPS, dated January 5, 2017 and September 26, 2017, addressed U.S. Patent Nos. 6,965,027 (expiring March 25, 2023) and RE41,783 (expiring December 8, 2025). The Orange Book also lists four additional patents for Xeljanz XR that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); and 7,301,023 (expiring May 23, 2022).

The '181 Patent

23. On April 10, 2018, the USPTO issued the '181 patent, titled "Tofacitinib Oral Sustained Release Dosage Forms." The '181 patent is duly and legally assigned to Pfizer Inc. A copy of the '181 patent is attached hereto as Exhibit A.

Sun's ANDA

24. By letter dated August 17, 2018 (the "Sun Notice Letter") and received by Pfizer on August 20, 2018, Sun notified Pfizer that it had filed ANDA No. 209790 with the FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Sun Generic XR Tablets – generic copies of Xeljanz XR (tofacitinib citrate EQ 11 mg base extended release tablets) – prior to the expiration of the '181 patent.

25. The Sun Notice Letter asserts that ANDA No. 209790 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) and that the '181 patent is "invalid, unenforceable and/or will not be infringed by" by Sun Generic XR Tablets.

26. The Sun Notice Letter indicates that Sun Generic XR Tablets will contain tofacitinib citrate as the active ingredient.

27. The Sun Notice Letter states that ANDA No. 209790 requests "approval to engage in the commercial manufacture, use or sale of" Sun Generic XR Tablets prior to the expiration of the '181 patent.

28. Attached to the Sun Notice Letter was Sun's Detailed Statement of the Factual and Legal Basis of Sun Pharmaceutical Industries Ltd.'s Opinion that the '181 Patent Is Invalid, Unenforceable, and/or Not Infringed ("Sun's Detailed Statement"), purportedly asserting "the detailed factual and legal bases for the Paragraph IV certification of Sun Pharmaceutical Industries Limited . . . that, in its opinion and to the best of its knowledge, [the '181 patent] is invalid and/or will not be infringed" by the commercial manufacture, use, or sale of Sun Generic XR Tablets.

29. Sun's Detailed Statement does not set forth a noninfringement argument with respect to any claim of the '181 patent.

30. Sun's Detailed Statement alleges that all claims of the '181 patent are invalid.

31. On information and belief, Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. collaborated and acted in concert in the decision to prepare and file and in the preparation and filing of ANDA No. 209790.

32. On information and belief, upon approval of ANDA No. 209790, Sun will distribute Sun Generic XR Tablets in the United States.

COUNT I
(Infringement of the '181 Patent by Sun Generic XR Tablets)

33. The allegations of paragraphs 1-32 above are repeated and re-alleged as if set forth fully herein.

34. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sun's filing of ANDA No. 209790 seeking approval to market Sun Generic XR Tablets was an act of infringement of at least claim 2 of the '181 patent, entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209790 be a date which is not earlier than the expiration date of the '181 patent.

35. Sun had knowledge of the '181 patent when it submitted ANDA No. 209790 to the FDA.

36. On information and belief, Sun intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sun Generic XR Tablets and will thereby infringe at least claim 2 of the '181 patent.

37. The foregoing actions by Sun constitute and/or would constitute infringement of at least claim 2 of the '181 patent.

38. Pfizer will be substantially and irreparably harmed if Sun is not enjoined from infringing the '181 patent. Pfizer has no adequate remedy at law.

COUNT II
(Sun Pharmaceutical Industries, Inc. Inducing of Infringement by Sun Pharmaceutical Industries Limited)

39. The allegations of paragraphs 1-38 above are repeated and re-alleged as if set forth fully herein.

40. On information and belief, Sun Pharmaceutical Industries, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed

the submission by Sun Pharmaceutical Industries Limited of ANDA No. 209790 to the FDA, knowing of the '181 patent.

41. The filing of ANDA No. 209790 by Sun Pharmaceutical Industries Limited constituted direct infringement under 35 U.S.C. § 271(e). Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Sun Pharmaceutical Industries, Inc. induced the infringement of the '181 patent by actively and knowingly causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the submission of ANDA No. 209790 to the FDA knowing that the submission of ANDA No. 209790 would constitute direct infringement of the '181 patent.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Sun Pharmaceutical Industries Limited's submission of ANDA No. 209790 was an act of infringement and that Sun's making, using, offering to sell, selling, or importing Sun Generic XR Tablets prior to the expiration of the '181 patent will infringe the '181 patent;

B. A judgment that defendant Sun Pharmaceutical Industries, Inc.'s knowing and purposeful activities causing to be submitted, and/or assisting with, participating in, contributing to, and/or directing the filing of ANDA No. 209790, knowing that its submission would constitute infringement of the '181 patent, induced the infringement of the '181 patent;

C. A judgment that the effective date of any FDA approval for Sun to make, use offer for sale, sell, market, distribute, or import the Sun Generic XR Tablets be no earlier than the date on which the '181 patent expires, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A permanent injunction enjoining Sun, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Sun Generic XR Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '181 patent, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

E. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

F. An award of Pfizer's costs and expenses in this action; and

G. Such further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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